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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/247,874	02/10/1999	GORDON W. DUFF	MSA-004.01	8151

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EXAMINER

SCINIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/26/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/248,757

Applicant(s)
Stone

Examiner
Richard Schnizer

Art Unit
1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 8, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34 and 46-69 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 and 46-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Feb 8, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

An amendment was received and entered as Paper No. 32 on 1/8/03.

New claims 58-69 were entered as requested.

Claims 34 and 46-69 are pending and under consideration in this Office Action.

Oath/Declaration

The submission of 1/8/03 is sufficient to overcome the objection to the declaration over the addition of an inventor.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 34 and 46-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the previous Office Action Applicant was informed that the paper copy of the sequence listing was not in agreement with the electronic copy (CRF) in that the CRF listed a C residue at

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position 8845 of SEQ ID NO:2, whereas the paper copy showed a G at position 8845 of SEQ ID NO:2. In Paper No. 32 Applicant amended the CRF to change the C at position 8845 of SEQ ID NO:2 to a G residue. However, the specification teaches that position 8845 of SEQ ID NO:2 should be a C residue. See page 4, lines 26 and 27 of the specification. It is noted that this passage refers to IL-1B allele 2 (+6912) position 2, rather than position 8845 of SEQ ID NO:2. According to the Examiner's understanding of the specification, by IL-1B allele 2 (+6912) position 2 is equivalent to position 8845 of SEQ ID NO:2. Because the specification teaches that position 8845 of SEQ ID NO:2 is a C residue, and the Sequence Listing has been amended such that position 8845 of SEQ ID NO:2 is now a G residue, the claims that recite SEQ ID NO:2 comprise new matter. This portion of the rejection can be overcome by submission of a new Sequence Listing in which position 845 of SEQ ID NO:2 is a C residue.

Applicant should provide:

A substitute computer readable form (CRF) copy of the "Sequence Listing".

A substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

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For CRF Submission Help, call (703) 308-4212

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Claims 46-57 have been amended to recite "said nucleic acid contains positions 8845-8850 of SEQ ID NO:2", and claims 57-69 now recite "nucleic acid which comprises between about 132 and 7000 consecutive nucleotides of SEQ ID NO:2, wherein said nucleic acid contains positions 8714-8845 of SEQ ID NO:2". The specification does not appear to provide literal support for these limitations. As set forth in MPEP 2163.06:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

Applicant's statements at page 3 of Paper No. 32, filed 1/8/03, to the effect that support can be found throughout the specification do not constitute specific guidance as to where in the specification support may be found for the amendments. Absent specific support in the specification, these limitations represent new matter.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-51, 53, 58-62, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No.G10509, published 8/15/95).

GenBank Accession No.G10509 teaches a sequence tagged site that is identical to bases 8340-8903 of SEQ ID NO:2. See attached sequence and partial alignment. The sequence was initially obtained as a PCR fragment, so it was double stranded and contained a complementary sequence. For this reason the isolate contained the complement recited in claim 53.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 46, 54-58, and 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession No.G10509 in view of Sambrook et al (1989).

GenBank Accession No.G10509 teaches a sequence tagged site that is identical to bases 8340-8903 of SEQ ID NO:2. See attached sequence and partial alignment.

GenBank Accession No.G10509 does not teach a nucleic acid comprising a label, a nucleic acid attached to a solid support, or a nucleic acid that is part of a probe array.

Sambrook teaches the dideoxy chain termination method of sequencing DNA. More specifically, Sambrook teaches that radiolabeled primers corresponding to a portion of the target sequence to be determined are synthesized and used to prime DNA synthesis, synthesized DNAs comprising fragments of the target sequence are separated by denaturing polyacrylamide gel electrophoresis resulting in a gel containing an array of labeled single stranded nucleic acids. The gel is subsequently transferred to a solid support (filter paper), prior to autoradiography. See page 13.6, paragraphs 1-3, page 13.9, paragraph 4, and pages 13.56 and 13.57, steps 6-10.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Sambrook in the process of determining the sequence of the nucleic acid of GenBank Accession No.G10509. One would have been motivated to do so because DNA sequencing methods can be considered to be obvious variants of one another, and the dideoxy method taught by Sambrook is considered to be the method of choice by those of skill in the art. See page 13.12, lines 6-9. In performing the method one necessarily would produce an array of

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labeled, single stranded fragments of bases 8340-8903 of SEQ ID NO:2, attached to a solid support.

Thus the invention as a whole was prima facie obvious.

Summary

Claims 46-51, 53-62, and 65-69 are anticipated or obvious.

Claims 34 and 46-69 recite new matter.

Claims 34, 52, 63, and 64 are free of the art of record.

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Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to

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the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

3/27/03

JEFFREY SIEW
PRIMARY EXAMINER